

REMARKS

Claims 1-18 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for the use of the term “rapidly expanding,” and under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,952,370 to Cummings, *et al.* (“Cummings”) in view of U.S. Patent No. 6,572,819 B1 to Wu, *et al.* (“Wu”).

In addition, double-patenting rejections have been entered against the pending claims in view of the claims in co-pending applications Ser. Nos. 09/941,925, 10/363,546 and 10/804,292.

1. The § 112 Issue Will Be Addressed By The Amendments.

The Applicants are requesting entry of an amendment to claim 1 to clarify that the recited rapid expansion occurs abruptly, *i.e.*, “wherein expanding and condensing the vapor compound takes place within several tenths of a second up to several seconds.” A similar amendment to independent claim 11 is also requested. No new matter is added by these amendments, as typical time frames for such expansion are discussed in the original specification. *See, e.g.*, Specification at 1 (third paragraph: “... a matter of tenths of a second, in particular in the case of sudden, adiabatic expansion, or several seconds in the case of other embodiments of the evaporator required for this purpose”).

Entry of these amendments and withdrawal of the pending § 112, second paragraph rejection is respectfully requested.

2. Claim 1 Is Distinguishable Over The Cited References.

As noted in the Applicants’ February 22, 2005 Amendment, the claimed invention provides an apparatus and method in which an aqueous hydrogen peroxide solution is abruptly expanded, such that resulting over-saturated vapor

nearly instantaneously forms a condensate film on the surfaces of the objects to be sterilized.

In contrast, Cummings teaches a relatively long sterilization process, in which hydrogen peroxide is essentially continuously injected into a chamber to contact objects whose surfaces are held initially cooler than the incoming vapor. A significant amount of time is required for the gradual condensation of the vapor onto the cooler objects, during which additional vapor is also continuously injected into the sterilization chamber (necessary in order to maintain a sufficient concentration of hydrogen peroxide on the object surface as the hydrogen peroxide both disassociates and evaporates).

The Cummings approach is further complicated by the need to carefully maintain the water-removing vacuum between the evaporation point of water and the evaporation point of hydrogen peroxide, and to continuously cool the objects' surface to ensure surface temperatures do not rise. Cummings at 2:41-64 ("The vapor phase hydrogen peroxide is continued to be introduced into the chamber until the surfaces are sterile while preserving the temperature ranges of both the first [10°C] and second [20°C] portions of the surfaces."); 3:47-54 (vacuum established to preferentially extract water); 3:55-60 ("injections of vapor phase hydrogen peroxide continue, thereby establishing a flow through the system"); 5:57-7:7 (full process description). Thus, unlike the present abrupt expansion approach, Cummings disadvantageously requires considerable time to achieve the desired sterilization. *See, e.g.*, Cummings at 6:14-16 (initial vapor introduction "for approximately one minute"); 6:44-48 (subsequent additional hydrogen peroxide injections over 4 to 32 minutes).

Because Cummings does not teach or suggest claim 1's abrupt vapor expansion in order to quickly apply a condensate film to an object (*i.e.*, on the order of minutes, not a "within several tenths of a second up to several seconds"), this reference fails to teach or suggest all the features of the present claims for which it is cited. The deficiencies of Cummings are not cured by the Wu reference, which is directed to various arrangements of a rack which is placed in a sterilization chamber to hold objects to be sterilized, but does not contain any suggestion of the present inventive rapid vapor expansion.

In view of the foregoing, the Applicants respectfully submit that claims 1-18 are patentable over Cummings and Wu under § 103(a). Reconsideration and withdrawal of the pending § 103(a) rejection of claims 1-18 is respectfully requested.

3. Withdrawal Of The Double Patenting Rejections Is Requested.

The Applicants respectfully traverse the pending provisional double patenting rejections of the claims over claims 1-20 of co-pending Application Ser. No. 09/941,925, claims 1-18 of co-pending Application Ser. No. 10/759,071 and claims 1-8 of co-pending Application Ser. No. 10/806,292, on the grounds that these claims are patentably distinct from the present invention.

Application Ser. No. 10/363,546: The claims of the present Application rely on the abrupt (on the order of tenths of a second to several seconds) adiabatic expansion of the sterilizing vapor to cause the vapor to condense and deposit on the objects to be sterilized. In the '546 Application, rather than the present claims' *decreasing* vapor pressure and temperature by adiabatic expansion, claims 1-16 recite the use of *increasing* vapor pressure to cause vapor

condensation, a feat which cannot be achieved by adiabatic expansion. *See also*, '546 Application Specification ¶[0008] (vapor pressure increase recited further resulting from continuous supply of the sterilization mixture into the sterilization chamber requiring sufficient time for the build-up of vapor pressure in the chamber, not from an abrupt expansion process). The pending claims and the claims of the '925 '71 Applications therefore are patentably distinct over one another.

Application Ser. No. 09/941,925: In the Amendment filed February 22, 2005, the Applicants noted that the claims of the present invention are directed to the use of a low-heat conducting, non-adsorptive material for the structure of a sterilization chamber. This development significantly improves sterilization performance in the present abrupt vapor expansion process by minimizing depletion of the vapor volume due to condensation on wall surfaces, in order to maximize the amount of vapor available to be deposited on the target objects – an improvement not taught or suggested in the '925 Application.

The pending rejection asserts, without identifying any support, that use of non-heat conducting chamber materials was “intrinsic” to the recited sterilization process. Yet nothing in the '925 Application provides *any* suggestion that any particular type of chamber wall material must “intrinsically” (or “naturally” or “inherently”) be used with the disclosed abrupt expansion sterilization process. Indeed, there is no discussion whatsoever any such wall heat transfer concerns in the '925 Application, let alone any suggestion that the presently claimed wall materials are “inherently” needed to reduce heat transfer from the chamber walls. Moreover, there is nothing in the '925 Application which

would suggest that any particular material is *needed* for the sterilization process to be successful, *i.e.*, that a particular material is “intrinsically” required to support the abrupt expansion sterilization process. The only arguably “intrinsic” aspect of the ‘925 Application is the need for walls to be present to define the chamber – but a teaching of the use walls does not by itself translate into a suggestion that the presently claimed wall *materials* are “intrinsic” to the use of the recited process.

Because the present claims are drawn to an improvement over the ‘925 Application which is neither intrinsic nor otherwise suggested therein, the Applicants respectfully submit that a *prima facie* showing of obviousness of the present claims over the ‘925 claims has not been made. Accordingly, reconsideration and withdrawal of the pending provisional double-patenting rejection based on the ‘925 Application is respectfully requested.

Application Ser. No. 10/806,292: As with the claims of the ‘925 Application above, there is nothing in the ‘292 Application which provides any suggestion of the features of the present claims, nor would it have been obvious to obtain the invention recited in the present claims starting from the ‘292 Application disclosure.

As noted above, the present claims improve on the abrupt vapor expansion process by the use of a low-heat conducting, non-adsorptive material for the structure of a sterilization chamber, thereby minimizing condensation of the vapor on the walls when the vapor abruptly expands. In contrast, where the present approach provides a passive approach to avoiding wall condensation by preventing excessive wall *cooling* of the vapor, the ‘292 Application is directed to

heating of “at least one of the surfaces of the objects to be sterilized and the sterilization chamber.” The ‘292 Application further teaches that this pre-heating is done to *enhance evaporation* of the sterilizing material *from the objects as well as the walls*. *See, e.g.*, ‘292 Application at ¶[0007]-[0010]. In other words, the ‘292 Application contains no teaching or suggestion of the present claims’ approach to maximizing the amount of vapor available to *condense* on the target objects (by use of particular wall materials). Rather, the ‘292 Application’s teachings of heating of the objects to enhance *evaporation* from the target objects teaches *away* from enhancing vapor *condensation* on the targets.

Thus, like the ‘925 Application, because the present claims are drawn to an improvement of the abrupt vapor expansion sterilization process which is not suggested by, or otherwise obvious in view of, the ‘292 Application, the Applicants respectfully submit that a *prima facie* showing of obviousness of the present claims over the ‘292 claims has not been made. Reconsideration and withdrawal of the pending provisional double-patenting rejection based on the ‘292 Application is respectfully requested.

CONCLUSION

In view of the foregoing, the Applicants respectfully submit that on entry of the requested amendments, claims 1-18 would be in condition for allowance. Early and favorable consideration and issuance of a Notice of Allowance for claims 1-18 is respectfully requested.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029082.53055US).

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Respectfully submitted,



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